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DATE: APRIL 5, 2005

NUMBER OF PAGES (INCLUDING  
THIS TRANSMITTAL COVER SHEET): 14

OUR REFERENCE: 231101

FROM: JOHN KILYK, JR./KAS  
REGISTRATION NO. 30,763

DIRECT LINE: (312) 616-5665

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FACSIMILE NUMBER: (571) 273-0459

IN RE APPLN. OF: TAYLOR ET AL  
APPLICATION NO. 10/510,065  
FILED: October 4, 2004  
FOR: STIMULATION OF NERVE CELL REGENERATION

Adjustment Date: 05/18/2005 CSM00T  
02/22/2005 PKIDWELL 00000000 121216 10510065  
01 FC:1615 300.00 CR

ATTORNEY DOCKET: 231101

**ATTACHED PLEASE FIND THE FOLLOWING DOCUMENTS:**

REQUEST FOR REFUND (2 PAGES IN DUPLICATE)  
COPY OF FIRST TRANSMITTAL LETTER (3 PAGES, ORIGINALLY SUBMITTED OCT. 6, 2004)  
COPY OF PRELIMINARY AMENDMENT (5 PAGES, ORIGINALLY SUBMITTED OCT. 6, 2004)  
COPY OF RETURN RECEIPT POSTCARD AND EXPRESS MAIL LABEL NO. EV 419249555 US

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PATENT  
Attorney Docket No. 231101  
Client Reference No. P030244US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Taylor et al.

Application No. 10/510,065

Art Unit: Unassigned

Filed: October 4, 2004

Examiner: Unassigned

For: STIMULATION OF NERVE CELL REGENERATION

**REQUEST FOR REFUND**

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Attn: Refund Section, Accounting Division

Sir:

☒ On February 22, 2005, the U.S. Patent and Trademark Office erroneously charged our firm's Deposit Account No. 12-1216 a "multiple dependent claim" fee (\$300) and a "total claims over twenty" fee (\$18). Please note that Applicants submitted a Preliminary Amendment with the initial filing of the application on October 4, 2004. The Preliminary Amendment removed all of the multiple dependencies in the claims while maintaining the total number of claims at twenty. Copies of the following documents are attached as evidence:

1. The Preliminary Amendment, submitted on October 4, 2004.
2. The Transmittal Letter to the US Designated/Elected Office, indicating the enclosure of a Preliminary Amendment and reciting Express Mail Label No. EV 419249555 US, submitted on October 4, 2004
3. The return receipt postcard, stamped and returned by the U.S. Patent and Trademark Office acknowledging receipt of the Preliminary Amendment on October 4, 2004.
4. The Express Mail Label No. EV 419249555 US, indicating the October 4, 2004 mailing date of the above-identified documents.

**Refund Request**


- ☒ This request for refund is made within two years of the date a fee was paid in this application on February 22, 2005 in the amount of \$318.00.

**Fees Paid**

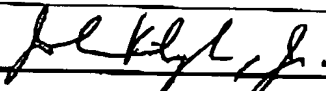
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Filing Fee	
<input checked="" type="checkbox"/> National Stage Claims - multiple dependent	\$300.00
National Stage Claims - extra total (over twenty)	\$18.00
<b>TOTAL REFUND REQUESTED</b>	<b>\$318.00</b>

Please make the refund by ☒ crediting Deposit Account No. 12-1216 or ☐ forwarding a check in the amount of the refund to the address below.

Respectfully submitted,

  
John Kilyk, Jr., Reg. No. 30,765  
LEYDIG, VOIT & MAYER, LTD.  
Two Prudential Plaza, Suite 4900  
180 North Stetson Avenue  
Chicago, Illinois 60601-6780  
(312) 616-5600 (telephone)  
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Date: April 5, 2005

<b>CERTIFICATE OF MAILING OR TRANSMISSION UNDER 37 CFR 1.8</b>			
I hereby certify that this Request for Refund and all accompanying documents are, on the date indicated below, <input checked="" type="checkbox"/> being facsimile transmitted to the U.S. Patent and Trademark Office, PCT Legal Department, Facsimile Number 571-273-0459.			
Name (Print/Type)	John Kilyk, Jr.		
Signature		Date	April 5, 2005

REFUND (Rev. 3/29/05)

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ATTORNEY DOCKET NO. 231101  
CLIENT REF. NO. P030244US  
U.S. APPLICATION NO. Unassigned

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 USC 371 AND 37 CFR 1.491**

INTERNATIONAL APPLICATION NO.  
PCT/GB03/01498

INTERNATIONAL FILING DATE  
4 April 2003 (04.04.2003)

PRIORITY DATE CLAIMED  
4 April 2002 (04.04.2002)

**TITLE OF INVENTION STIMULATION OF NERVE CELL REGENERATION**

**APPLICANT(S) FOR DO/EO/US TAYLOR, Jeremy Simon Hudson; BAMPTON, Edward Thomas William**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 USC 371 and 37 CFR 1.491.
  2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 USC 371 and 37 CFR 1.491.
  3. ☒ This is an express request to begin national examination procedures (35 USC 371(f)).
  4. ☒ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
  5. ☒ A copy of the International Application as filed (35 USC 371(c)(2))
    - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
    - b. ☒ has been communicated by the International Bureau.
    - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
  - ☐ An English language translation of the International Application as filed (35 USC 371(c)(2)).
  7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3))
    - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
    - b. ☐ have been communicated by the International Bureau.
    - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
    - d. ☒ have not been made and will not be made.
  8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3)).
  9. ☐ An oath or declaration of the inventor(s) (35 USC 371(c)(4)).
  10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)).
  11. Nucleotide and/or Amino Acid Sequence Submission
    - a. ☒ Computer Readable Form (CRF)
    - b. Specification Sequence Listing on:
      - i. ☐ CD-ROM or CD-R (2 copies); or
      - ii. ☒ Paper Copy
    - c. ☒ Statement verifying identity of above copies
- Items 12 to 19 below concern other document(s) or information included:
12. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
    - ☐ Form PTO-1449
    - ☐ Copies of References (except for U.S. patents and applications)
  13. ☐ An assignment for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
  14. ☒ A **FIRST** preliminary amendment.
    - ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
  15. ☐ A substitute specification.
  16. ☐ A change of power of attorney and/or address letter.
  17. ☒ Application Data Sheet Under 37 CFR 1.76
  18. ☒ Return Receipt Postcard
  19. ☐ Other items or information:

U.S. APPLICATION NO. Unassigned		INTERNATIONAL APPLICATION NO. PCT/GB03/01498		ATTORNEY DOCKET NO. 231101		CLIENT REF. NO. P030244US	
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20. The following fees are submitted:

☒ **Basic National Fee (37 CFR 1.492(a)(1)-(5)):**  
 Neither international preliminary examination fee (37 CFR 1.482)  
 nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO  
 and International Search Report not prepared by the EPO or JPO.....\$1,110.00  
 International preliminary examination fee (37 CFR 1.482) not paid to  
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 but international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....\$790.00  
 International preliminary examination fee paid to USPTO (37 CFR 1.482)  
 but all claims did not satisfy provisions of PCT Article 33(1)-(4).....\$750.00  
 International preliminary examination fee paid to USPTO (37 CFR 1.482)  
 and all claims satisfied provisions of PCT Article 33(1) to (4).....\$100.00

**ENTER APPROPRIATE BASIC FEE AMOUNT=** \$950.00

CLAIMS		NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	20	-20=	0	x \$ 18.00	\$0.00	
Independent Claims	4	- 3 =	1	x \$ 88.00	\$88.00	
<input type="checkbox"/> Multiple Dependent Claim(s) (if applicable)				+ \$300.00	\$	
<input type="checkbox"/> Surcharge of \$130.00 for furnishing the National fee or oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date					\$	
<b>TOTAL OF ABOVE CALCULATIONS=</b>					\$1,038.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.					\$ ( )	
<b>SUBTOTAL=</b>					\$1,038.00	
<input type="checkbox"/> Processing fee of \$130.00 for furnishing English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date.					\$	
<b>TOTAL NATIONAL FEE=</b>					\$1,038.00	
<input type="checkbox"/> Fee for recording the enclosed assignment. The assignment must be accompanied by an appropriate cover sheet. \$40.00 per property					+	\$
<b>TOTAL FEE=</b>					\$1,038.00	
					Amount to be: refunded	\$
					charged:	\$

a. ☐ No fee is believed to be due.


b. ☒ Please charge Deposit Account No. 12-1216 the total fee indicated above.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to  
Deposit Account No. 12-1216. A duplicate copy of this sheet is enclosed.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR  
1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO CUSTOMER NO.  
23460:

23460

  
 John Kilyk, Jr., Registration No. 30,763  
 Leydig, Voit & Mayer, Ltd.  
 Two Prudential Plaza, Suite 4900  
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 (312) 616-5600 (telephone)  
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 Date: October 4, 2004

U.S. APPLICATION NO. Unassigned	INTERNATIONAL APPLICATION NO. PCT/GB03/01498	ATTORNEY DOCKET NO. 231101	CLIENT REF. NO. P030244US
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**CERTIFICATION UNDER 37 CFR 1.10**

"Express Mail" Label Number: EV 419249555 US

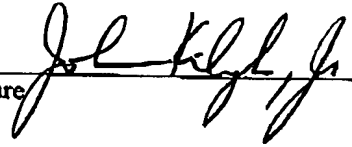
Date of Deposit: October 4, 2004

I hereby certify that this express request to begin national examination procedures under 35 USC 371(f) of the International Patent Application referenced above, including all of the items listed thereon as enclosures, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

John Kilyk, Jr.

Printed Name of Person Signing:

Signature



**PATENT**  
Attorney Docket No. 231101  
Client Reference No. P030244US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Taylor et al.

Application No. Unassigned

Art Unit: Unassigned

Filed: October 4, 2004

Examiner: Unassigned

For: STIMULATION OF NERVE CELL  
REGENERATION

**PRELIMINARY AMENDMENT**

**COPY**

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Prior to the examination of the above-identified patent application, please enter the following amendments and consider the following remarks.

In re Appln. of Taylor et al.  
Application No. Unassigned

*CLAIM AMENDMENTS*

1. (Original) A method for stimulating the regeneration of a neuronal cell, said method comprising exposing the cell to the osteonectin protein or a functional equivalent thereof in an amount that is effective to stimulate the regeneration of the cell.
2. (Original) A method according to claim 1, wherein the neuronal cell is a CNS neuronal cell.
3. (Currently Amended) A method according to claim 1 ~~or claim 2~~, wherein the cell is exposed to the osteonectin protein or functional equivalent thereof *in vitro*.
4. (Currently Amended) A method according to claim 1 ~~or 2~~, where the cell is exposed to the osteonectin protein or functional equivalent thereof *in vivo* in a patient.
5. (Original) A method according to claim 4, wherein the neuronal cell is exposed to the osteonectin protein or functional equivalent thereof through the introduction into a patient of a nucleic acid molecule that expresses the osteonectin protein or functional equivalent thereof.
6. (Original) A method according to claim 5, wherein the neuronal cell is exposed to the osteonectin protein or a fragment or variant thereof through the introduction into a patient of a cell that contains the nucleic acid molecule which expresses the osteonectin protein or a functional equivalent thereof in a therapeutically-effective amount.
7. (Original) A method according to claim 4, wherein said neuronal cell is exposed to a pharmaceutical composition comprising the osteonectin protein or functional equivalent thereof in an amount appropriate to stimulate the regeneration of the cell.
8. (Original) A method according to claim 7, wherein said pharmaceutical composition comprises a cell which expresses the osteonectin protein or a functional equivalent thereof.
9. (Currently Amended) A method according to claim 6 ~~or claim 8~~, wherein said cell is derived from the patient being treated.
10. (Currently Amended) A method according to ~~any one of the preceding claims~~ claim 1, wherein said neuronal cell is exposed to the osteonectin protein or functional equivalent thereof in the presence of one or more additional neurotrophic factors.



In re Appln. of Taylor et al.  
Application No. Unassigned

11. (Original) A method according to claim 10, wherein said one or more neurotrophic factors is selected from the group consisting of nerve growth factor, glial derived growth factor, brain derived growth factor, ciliary neurotrophic factor, neurotrophin-3, vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF) and platelet-derived growth factor (PDGF).

12. (Currently Amended) A method according to ~~any one of the preceding~~ claims claim 1, wherein said neuronal cell is exposed to the osteonectin protein or functional equivalent thereof impregnated into an artificial bridging substrate which is placed at or near the site in the body at which neuronal regeneration is required.

13. (Original) A method according to claim 12, wherein said artificial bridging substrate is Elvax®.

14. (Currently Amended) A method according to ~~any one of the preceding~~ claims claim 1, wherein said stimulation of the regeneration of a neuronal cell is in the context of the treatment of a disease selected from the group consisting of peripheral neuron damage, such as by physical injury or disease state such as diabetes, in the case of injury or a disease state of the CNS, including physical damage to the spinal cord, brain trauma, stroke, retinal and optic nerve lesions, neurodegenerative diseases such as Alzheimer's disease and Parkinson's disease, neuromuscular diseases, autoimmune diseases of the nervous system, tumours of the central nervous system, damage to motor neurons such as occurs in amyotrophic lateral sclerosis, retinitis pigmentosa or age-related macular degeneration.

15. (Original) Use of the osteonectin protein or a functional equivalent thereof in the manufacture of a medicament for the stimulation of neuronal cell regeneration, preferably, for the stimulation of CNS neuronal cell regeneration.

16. (Original) Use according to claim 15, wherein said osteonectin protein or a functional equivalent thereof is used in the manufacture of a medicament for the treatment of peripheral nerve damage, such as by physical injury or disease state such as diabetes, in the case of injury or a disease state of the CNS, including physical damage to the spinal cord, brain trauma, stroke, retinal and optic nerve lesions, neurodegenerative diseases such as Alzheimer's disease and Parkinson's disease, neuromuscular diseases, autoimmune diseases of the nervous system, tumours of the central nervous system, damage to motor neurons such as occurs in amyotrophic lateral sclerosis, and retinitis pigmentosa and age-related macular degeneration.

In re Appln. of Taylor et al.  
Application No. Unassigned

17. (Original) A method of screening for a receptor protein that mediates the stimulation of neuronal cell regeneration, said method comprising exposing a cell to osteonectin, cross-linking the osteonectin protein to a receptor on the cell, and analyzing the complex to identify the receptor.

18. (Original) A method of screening for a receptor protein that mediates the stimulation of neuronal cell regeneration, said method comprising contacting a candidate cell with the osteonectin protein or a functional equivalent thereof and assessing the ability of the cell to effect stimulation of neuronal cell regeneration.

19. (Original) A method according to claim 18, wherein a library of candidate cells is exposed to the osteonectin protein or a functional equivalent thereof.


20. (Original) A method according to claim 19, wherein said library of candidate cells has been transformed with a library of nucleic acid molecules, each nucleic acid molecule encoding a candidate receptor for osteonectin.

*REMARKS*

The claims have been amended to comport with U.S. patent practice by removing multiply-dependent claims. No new matter has been added by way of these claim amendments.

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

  
John Kilyk, Jr., Reg. No. 307763  
LEYDIG, VOIT & MAYER, LTD.  
Two Prudential Plaza, Suite 4900  
180 North Stetson Avenue  
Chicago, Illinois 60601-6780  
(312) 616-5600 (telephone)  
(312) 616-5700 (facsimile)

Date: October 4, 2004

THE PATENT AND TRADEMARK OFFICE IS RESPECTFULLY REQUESTED TO PLACE ITS STAMP ON THIS POSTAL CARD AND PLACE IT IN THE OUTGOING MAIL TO SHOW THE FOLLOWING PAPERS HAVE BEEN RECEIVED.

## VIA EXPRESS MAIL

MAILING/FILING DATE: October 4, 2004  
APPLICATION OF: TAYLOR et al.

DOCKET NO.: 231101  
CLIENT: Carpmals

EXPRESS MAIL NO: EV 419249555 US

TITLE: ~~NEW BLOOD SUGAR CONTROLLER AND METHOD OF SCREENING THE SAME~~

APPLICATION NO. Unassigned

JKJ/kas

- ☒ Transmittal Letter to the U.S. Designated/Elected Office [Total Pages 3 (in duplicate)];
- ☒ Application Data Sheet [Total Pages 3];
- ☒ Specification [Total Pages 34];
- ☒ Claims [Total Pages 3];
- ☒ Abstract [Total Pages 1];
- ☒ Preliminary Amendment [Total Pages 7];
- ☒ Submission of Sequence Listing [Total Pages 1];
- ☒ Sequence Listing [Total Pages 1];
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